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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/025,273 | 12/18/2001 | Tamea Rae Sisco | 123p-Real | 5651 |

7590 05/20/2005

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| EXAMINER |
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WEBMAN, EDWARD J

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| ART UNIT | PAPER NUMBER |
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1616

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/025,273 | Applicant(s) Sisco et al. | |
| | Examiner Edward J. Webman | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18, 21-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beigler et al.

Beigler et al teach an intravenous nutrient composition (title). Amino acids, minerals, vitamins and mixtures thereof are taught (column 4 lines 49-51). A mixture of four minerals, including zinc sulfate are specified (column 10 example 3). A mixture of three amino acids, including riboflavin, is disclosed (column 11 example 4). A mixture of three amino acids is specified (column 11 example 5).

It would have been obvious to one of ordinary skill to make a composition comprising amino acids, minerals, vitamins and mixtures thereof to obtain the beneficial effect of intravenous use in view of Beigler et al. As to the claimed saline solution and osmolality, such would also be an obvious expedient in an intravenous composition.

Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beigler et al in view of Iwagiri et al.

Beigler et al is discussed above. They do not teach mecobalamin.

Iwagiri et al teach mecobalamin is a coenzyme B12 included in the blood (column 1 lines 17-18).

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It would have been obvious to one of ordinary skill to use mecobalamin in the composition of Beigler et al to achieve the beneficial effect of vitamin B12 in the blood.

Applicants argue that Iwagiri et al teach a solid composition. However, Iwagiri et al is cited only for its teaching that mecobalamin is found in the blood.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beigler et al in view of Winitz et al '287.

Beigler et al is discussed above. They do not teach riboflavin-5-phosphate.

Winitz et al '287 teach an aqueous emulsion containing amino acids, minerals, and vitamins (abstract). Riboflavin phosphate sodium salt is disclosed as a water-soluble vitamin (column 10 lines 38 and 59).

It would have been obvious to one of ordinary skill to use riboflavin phosphate as the riboflavin of the Beigler et al intravenous composition in view of the teaching in Winitz et al '287 that the phosphate is water-soluble. As to the particularly claimed riboflavin-5-phosphate, such is the item of commerce available as riboflavin phosphate.

Claims 1-21, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.


It is unclear whether the claims are directed to a single composition or a kit of separate compositions.

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.



**EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500**